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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,178	01/15/2002	Jean-Paul Briand	110072	8029

7590 10/07/2004

Oliff & Berridge
PO Box 19928
Alexandria, VA 22320

EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,178	BRIAND ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *12-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/01, 09/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-11, and 18 in the reply filed on 07/21/2004 is acknowledged. The traversal is on the ground(s) that the Examiner did not make it clear whether there was a special technical feature that ran through the respective groups or was not a special technical feature that ran through the groups. The Examiner apologizes for any miscommunication on the issue and hereby clarifies that there was not a special technical feature that ran through the respective groups (an attempt was made to find a special technical feature among the formula's, but since distinct formula's were found requiring distinct searches, no special technical feature thus ran through the respective groups). Therefore, unity of invention was not present and restriction proper. Applicant argues that there is a single inventive concept in the present case, however, this is not found persuasive because absent a special technical feature there can be no single inventive concept between the respective groups defined in a restriction requirement. The requirement is still deemed proper and is therefore made FINAL.

Notwithstanding the foregoing, the Examiner was willing, at this time, to attempt a reasonable search/examination of broad claim 1 in its entirety (although containing distinct formulas/compounds thereto which Applicant was required to elect in response hereto), as drawn to the elected Group I. Claims 1-11 and 18 are herein examined on the merits and claims 12-17 withdrawn from further consideration.

Claim Rejections - 35 USC § 112 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention, and claims 1-11, and 18 is drawn to pseudopeptides of formula I and II, methods of making such, and reagents and kits using said pseudopeptides.

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the claimed invention. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Namely, although the specification and claims describe that any 6 amino acids (claim 1), or 9 amino acids (claim 2), or 12 amino acids (claim 10) may constitute the pseudopeptide built around the core of formula's I and II of claim 1, Applicant has not shown

/described what specific peptide (common/uncommon) are to used at what residue of such contemplated pseudopeptides; the method of making such, and whether any such pseudopeptide would be useable in the reagent/kit of the invention.

Thus, neither the claims nor the specification details what specific peptide (common/uncommon) are to used at what residue of such contemplated pseudopeptides; the method of making such, and whether any such pseudopeptide would be useable in the reagent/kit of the invention.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112 1st Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while it may be enabling for treating and/or reducing the risk of a bone disorder or a bone disorder that results in weakened bones, does not reasonably provide enablement for preventing any bone disorder or any bone disorder that results in weakened bones using such a composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have

interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for any 6 amino acids (claim 1), or 9 amino acids (claim 2), or 12 amino acids (claim 10) pseudopeptide (or method of making, or reagent/kit containing) built around the core of formula's I and II of claim 1, for the following reasons:

The nature of the invention: Any 6 amino acids (claim 1), or 9 amino acids (claim 2), or 12 amino acids (claim 10) pseudopeptide of formula I and II, methods of making such, and reagents and kits using said pseudopeptides.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that a single amino acid substitution can alter the antigen-binding specificity of peptides, and thus alter peptide function either in vitro or in vivo (i.e. "in a subject") (Rudikoff et al., Proc Natl Acad Sci U S A. 1982 Mar;79(6):1979-83, page 1979, and page 1982, 1st s. under "Implications for Generation of Diversity").

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art.

In re Buchner 18 USPQ 2d 1331 (Fed. Cir. 1991). The specification broadly describes the making of any pseudopeptide of any 6 amino acids (claim 1), or 9 amino acids (claim 2), or 12 amino acids (claim 10) pseudopeptide built around the core of formula's I and II of claim 1, but not clearly show specific enabled embodiments thereof and whether any pseudopeptides can work in the reagent/kit of the invention.

The breadth of the claims and the quantity of experimentation needed: The claims are drawn to any 6 amino acids (claim 1), or 9 amino acids (claim 2), or 12 amino acids (claim 10) pseudopeptide of formula I and II, methods of making such, and reagents and kits using said pseudopeptides. As described above, with the substantial variability among the broad genus of pseudopeptides, due to their short length and the lack of reliability of the testing and results, it is not clear as whether any pseudopeptide within these parameters is clearly enabled by one of skill in the art, especially for use in a reagent/kit. As Rudikoff et al. teach, a single amino acid substitution may be enough to alter peptide specificity or function. Absent sufficient teachings in the specification to overcome the teachings of unpredictability found in the art, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA
10/1/04

CHRISTOPHER R. TATE
PRIMARY EXAMINER